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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,134	08/29/2005	Steven Jones	85084-402	3937

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EXAMINER	
HURT, SHARON L	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
11/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,134	JONES ET AL.	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,13-15,17,19-23,25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 13-15, 17, 19-23, 25 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendments to the claims filed June 24, 2009 have been acknowledged and entered. Claims 1, 13 and 21 are currently amended.

Status of the Claims

2. Claims 1-3, 5, 13-15, 17, 19-23, 25 and 27-31 are pending and under examination. Claims 4, 6-12, 16, 18, 24 and 26 have been cancelled.

Response to Arguments

3. Applicant's arguments filed June 24, 2009 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 13-15, 17, 19-23, 25 and 27-31 **stand** rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (1999) in view of Kahn et al. (2001) and Vanderzanden et al. (1998) for reasons of record in Paper No. 20090219 and as follows.

Ito teaches a recombinant vesicular stomatitis virus (VSV) expressing Ebola (viral hemorrhagic fever virus; VHF) glycoprotein wherein the mutation reduced the infectivity of the VSVΔG by incorporation of the Ebola virus glycoprotein into recombinant VSV particles (Abstract and page 8908, 2nd column) (*as it relates to claims 1-3, 5, 14, 15, 17, 22-23, 25 and 29-31*). However Ito does not teach a vaccine or a method of preparing a pharmaceutical composition.

Kahn teaches replication-competent vesicular stomatitis virus (VSV) expressing foreign respiratory syncytial virus (RSV) glycoproteins/antigens elicited RSV specific antibodies and protects mice against RSV challenge (Title and Abstract) (as *it relates to claim 1, 13 and 21*). Kahn teaches the VSV glycoprotein (G) gene was deleted from the full-length cDNA VSV genomic plasmids containing the RSV G gene such that the RSV G genes replaced VSV G in viral genome (page 11081, second column) (*as it relates to claims 1, 13 and 21*). The RSV G (attachment) is the first and major antigenic glycoprotein (page 11079, last paragraph) (*as it relates to claims 5, 17 and 25*). Kahn teaches a method of eliciting an immune response in mice by intranasal vaccination with a recombinant VSV expressing RSV G (Abstract) (*as it relates to claims 13, 20 and 28*). Kahn teaches about vaccine development and passive immunization with a recombinant VSV expressing RSV G (page 11079, last paragraph) (*as it relates to claim 21*). Purified RSV was harvested from baby hamster kidney cells and the antibodies were detected by ELISA after mice were inoculated intranasally with recombinant viruses (page 11080, third paragraph and page 11083, second and third paragraph). However Kahn does not teach VSV vector expressing a viral hemorrhagic fever virus glycoprotein (VHF).

Vanderzanden teaches a method of preparing DNA vaccines expressing the envelope glycoprotein (GP) of Ebola virus (EBOV) elicited antibody response and elicited cytotoxic T cell responses (Abstract) (*as it relates to claims 1-3, 13-15, 21-23 and 29-31*). Vanderzanden teaches EBOV GP is the most likely viral protein to elicit neutralizing antibodies, because it is the only protein known to be on the virion surface (p. 135, 1st col. 2nd full paragraph) (*as it relates to claims 1-3, 13-15, 21-23 and 29-31*). Vanderzanden teaches GP DNA was the most logical vaccine candidate (p. 136, 1st col. 1st full paragraph). Vanderzanden teaches only GP immunized animals were positive in cell proliferation and T cell growth factor assays (p. 140, 2nd col. 1st paragraph). However Vanderzanden does not teach a foreign glycoprotein replacing the native VSV glycoprotein.

In summary Ito teaches a recombinant VSV expressing Ebola glycoprotein. Kahn teaches a live replication-competent VSV expressing a major glycoprotein, a method of replacing VSV glycoprotein with another viral glycoprotein, and a method of eliciting an immune response with the recombinant VSV expressing a foreign glycoprotein. Vanderzanden teaches a method of preparing a vaccine expressing the Ebola surface glycoprotein and that glycoproteins are the most logical to use in a vaccine to induce antibodies and elicit an immune response.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to expand the teachings of Ito and prepare a vaccine comprising a VSV expressing the glycoprotein of a hemorrhagic virus such as Ebola using the methods of Kahn and Vanderzanden. The person of ordinary skill in the art would have been motivated to make use a VSV expressing the glycoprotein of a hemorrhagic virus to elicit an immune

response because Ito teaches it is effective with Ebola (VHF), Kahn teaches how to prepare the composition and Vanderzanden teaches producing a vaccine and suggests using the glycoprotein. Therefore a person of ordinary skill in the art would have reasonably expected success in generating a vaccine wherein the glycoprotein of VSV is replaced with a glycoprotein from a VHF because of the teachings of Ito, Kahn and Vanderzanden.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to complement the methods of vaccinating taught by Kahn and Vanderzanden and administer the vaccine orally (*as it relates to claims 19 and 27*) because Kahn teaches intranasal vaccination, which anatomically includes oral administration.

Response to Arguments

Applicants argue "neither Ito nor Kahn teach or suggest a live, replication competent VSV particle encoding a VHF glycoprotein". In response, Kahn teaches live replication-competent non-propagating VSV expressing foreign glycoprotein genes. Ito further teaches VSV expressing Ebola (VHF) glycoprotein, which also are reasonably live and replication competent, as claimed.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Hurt/
Examiner, Art Unit 1648
11/12/09

/Robert C. Hayes, Ph.D./
Primary Examiner, Art Unit 1649